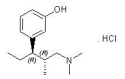
NUCYNTA - tapentadol hydrochloride tablet, film coated
Stat Rx USA

11 DESCRIPTION
NUCYNTA™ (tapentadol) Tablets are immediate-release film-coated tablets for oral administration. The chemical name is 3-[(1*R*,2*R*)-3-(dimethylamino)-1-ethyl-2-methylpropyl]phenol monohydrochloride. The structural formula is:



The molecular weight of tapentadol HCl is 257.80, and the molecular formula is $C_{14}H_{23}NO \cdot HCl$. The n-octanol:water partition coefficient log P value is 2.87. The pKa values are 9.34 and 10.45. In addition to the active ingredient tapentadol HCl, tablets also contain the following inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, povidone, magnesium stearate, and Opadry® II, a proprietary film-coating mixture containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and aluminum lake coloring.
12 CLINICAL PHARMACOLOGY12.1 Mechanism of Action
Tapentadol is a centrally-acting synthetic analgesic. Although its exact mechanism is unknown, analgesic efficacy is thought to be due to mu-opioid agonist activity and the inhibition of norepinephrine reuptake.
12.2 Pharmacodynamics
Tapentadol is a centrally-acting synthetic analgesic. It is 18 times less potent than morphine in binding to the human mu-opioid receptor and is 2–3 times less potent in producing analgesia in animal models. Tapentadol has been shown to inhibit norepinephrine reuptake in the brains of rats resulting in increased norepinephrine concentrations. In preclinical models, the analgesic activity due to the mu-opioid receptor agonist activity of tapentadol can be antagonized by selective mu-opioid antagonists (e.g., naloxone), whereas the norepinephrine reuptake inhibition is sensitive to norepinephrine modulators. Tapentadol exerts its analgesic effects without a pharmacologically active metabolite.
Effects on the cardiovascular system: There was no effect of therapeutic and supratherapeutic doses of tapentadol on the QT interval. In a randomized, double-blind, placebo- and positive-controlled crossover study, healthy subjects were administered five consecutive doses of NUCYNTA™ 100 mg every 6 hours, NUCYNTA™ 150 mg every 6 hours, placebo and a single oral dose of moxifloxacin. Similarly, NUCYNTA™ had no relevant effect on other ECG parameters (heart rate, PR interval, QRS duration, T-wave or U-wave morphology).
12.3 Pharmacokinetics
Absorption
Mean absolute bioavailability after single-dose administration (fasting) is approximately 32% due to extensive first-pass metabolism. Maximum serum concentrations of tapentadol are typically observed at around 1.25 hours after dosing.
Dose-proportional increases in the C_{max} and AUC values of tapentadol have been observed over the 50 to 150 mg dose range.
A multiple (every 6 hour) dose study with doses ranging from 75 to 175 mg tapentadol showed a mean accumulation factor of 1.6 for the parent drug and 1.8 for the major metabolite tapentadol-O-glucuronide, which are primarily determined by the dosing interval and apparent half-life of tapentadol and its metabolite.
Food Effect
The AUC and C_{max} increased by 25% and 16%, respectively, when NUCYNTA™ was administered after a high-fat, high-calorie breakfast. NUCYNTA™ may be given with or without food.
Distribution
Tapentadol is widely distributed throughout the body. Following intravenous administration, the volume of distribution (Vz) for tapentadol is 540 +/- 98 L. The plasma protein binding is low and amounts to approximately 20%.
Metabolism and Elimination
In humans, the metabolism of tapentadol is extensive. About 97% of the parent compound is metabolized. Tapentadol is mainly metabolized via Phase 2 pathways, and only a small amount is metabolized by Phase 1 oxidative pathways. The major pathway of tapentadol metabolism is conjugation with glucuronic acid to produce glucuronides. After oral administration approximately 70% (55% O-glucuronide and 15% sulfate of tapentadol) of the dose is excreted in urine in the conjugated form. A total of 3% of drug was excreted in urine as unchanged drug. Tapentadol is additionally metabolized to N-desmethyl tapentadol (13%) by CYP2C9 and CYP2C19 and to hydroxy tapentadol (2%) by CYP2D6, which are further metabolized by conjugation. Therefore, drug metabolism mediated by cytochrome P450 system is of less importance than phase 2 conjugation.
None of the metabolites contributes to the analgesic activity.
Tapentadol and its metabolites are excreted almost exclusively (99%) via the kidneys. The terminal half-life is on average 4 hours after oral administration. The total clearance is 1530 +/- 177 ml/min.
Special Populations
Elderly
The mean exposure (AUC) to tapentadol was similar in elderly subjects compared to young adults, with a 16% lower mean C_{max} observed in the elderly subject group compared to young adult subjects.
Renal Impairment

AUC and C_{max} of tapentadol were comparable in subjects with varying degrees of renal function (from normal to severely impaired). In contrast, increasing exposure (AUC) to tapentadol-O-glucuronide was observed with increasing degree of renal impairment. In subjects with mild, moderate, and severe renal impairment, the AUC of tapentadol-O-glucuronide are 1.5-, 2.5-, and 5.5-fold higher compared with normal renal function, respectively.

Hepatic Impairment

Administration of NUCYNTA™ resulted in higher exposures and serum levels to tapentadol in subjects with impaired hepatic function compared to subjects with normal hepatic function. The ratio of tapentadol pharmacokinetic parameters for the mild and moderate hepatic impairment groups in comparison to the normal hepatic function group were 1.7 and 4.2, respectively, for AUC; 1.4 and 2.5, respectively, for C_{max}; and 1.2 and 1.4, respectively, for $t_{1/2}$. The rate of formation of tapentadol-O-glucuronide was lower in subjects with increased liver impairment.

Pharmacokinetic Drug Interactions

Tapentadol is mainly metabolized by Phase 2 glucuronidation, a high capacity/low affinity system, therefore, clinically relevant interactions caused by Phase 2 metabolism are unlikely to occur. Naproxen and probenecid increased the AUC of tapentadol by 17% and 57%, respectively. These changes are not considered clinically relevant and no change in dose is required.

No changes in the pharmacokinetic parameters of tapentadol were observed when acetaminophen and acetylsalicylic acid were given concomitantly.

In vitro studies did not reveal any potential of tapentadol to either inhibit or induce cytochrome P450 enzymes. Thus, clinically relevant interactions mediated by the cytochrome P450 system are unlikely to occur.

The pharmacokinetics of tapentadol were not affected when gastric pH or gastrointestinal motility were increased by omeprazole and metoclopramide, respectively.

Plasma protein binding of tapentadol is low (approximately 20%). Therefore, the likelihood of pharmacokinetic drug-drug interactions by displacement from the protein binding site is low.

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1 INDICATIONS AND USAGE
NUCYNTA™ (tapentadol) is indicated for the relief of moderate to severe acute pain in patients 18 years of age or older.
4 CONTRAINDICATIONS4.1 Impaired Pulmonary Function
Like other drugs with mu-opioid agonist activity, NUCYNTA™ is contraindicated in patients with significant respiratory depression in unmonitored settings or the absence of resuscitative equipment. NUCYNTA™ is also contraindicated in patients with acute or severe bronchial asthma or hypercapnia in unmonitored settings or the absence of resuscitative equipment *[see Warnings and Precautions (5.1)]*.
4.2 Paralytic Ileus
Like drugs with mu-opioid agonist activity, NUCYNTA™ is contraindicated in any patient who has or is suspected of having paralytic ileus.
4.3 Monoamine Oxidase Inhibitors
NUCYNTA™ is contraindicated in patients who are receiving monoamine oxidase (MAO) inhibitors or who have taken them within the last 14 days due to potential additive effects on norepinephrine levels which may result in adverse cardiovascular events *[see Drug Interactions (7.4)]*.
6 ADVERSE REACTIONS
The following treatment-emergent adverse events are discussed in more detail in other sections of the labeling:
• Respiratory Depression *[see Contraindications (4.1) and Warnings and Precautions (5.1)]*

• CNS Depression *[see Warnings and Precautions (5.2)]*

Because clinical studies are conducted under widely varying conditions, adverse event rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in clinical practice. A treatment-emergent adverse event refers to any untoward medical event associated with the use of the drug in humans, whether or not considered drug-related.
Based on data from nine Phase 2/3 studies that administered multiple doses (seven placebo- and/or active-controlled, one noncontrolled and one Phase 3 active-controlled safety study) the most common adverse events (reported by 10% in any NUCYNTA™ dose group) were: nausea, dizziness, vomiting and somnolence.

The most common reasons for discontinuation due to adverse events in the studies described above (reported by ≥1% in any NUCYNTA™ dose group) were dizziness (2.6% vs. 0.5%), nausea (2.3% vs. 0.6%), vomiting (1.4% vs. 0.2%), somnolence (1.3% vs. 0.2%) and headache (0.9% vs. 0.2%) for NUCYNTA™- and placebo-treated patients, respectively.
Seventy-six percent of NUCYNTA™-treated patients from the nine studies experienced adverse events.
NUCYNTA™ was studied in multiple-dose, active- or placebo-controlled studies, or noncontrolled studies (n = 2178), in single-dose studies (n = 870), in open-label study extension (n = 483) and in Phase 1 studies (n = 597). Of these, 2034 patients were treated with doses of 50 mg to 100 mg of NUCYNTA™ dosed every 4 to 6 hours.
The data described below reflect exposure to NUCYNTA™ in 3161 patients, including 449 exposed for 45 days. NUCYNTA™ was studied primarily in placebo- and active-controlled studies (n = 2266, and n = 2944, respectively). The population was 18 to 85 years old (mean age 46 years), 68% were female, 75% white and 67% were postoperative. Most patients received NUCYNTA™ doses of 50 mg, 75 mg, or 100 mg every 4 to 6 hours.
6.1 Commonly-Observed Treatment-Emergent Adverse Events in Double-Blind Controlled Clinical Trials
Table 1 lists the adverse events reported in 1% or more of NUCYNTA™-treated patients with acute moderate to severe pain in the pooled safety data from nine Phase 2/3 studies that administered multiple doses (seven placebo- and/or active-controlled, one noncontrolled, and one Phase 3 active-controlled safety study).
6.2 Other Adverse Reactions Observed During the Premarketing Evaluation of NUCYNTA™
The following adverse drug reactions occurred in 1% of NUCYNTA™-treated patients in the pooled safety data from nine Phase 2/3 studies that administered multiple doses (seven were placebo- and/or active-controlled, one noncontrolled, and one Phase 3 active-controlled safety study):
Cardiac disorders: heart rate increased, heart rate decreased
Eye disorders: visual disturbance
Gastrointestinal disorders: abdominal discomfort, impaired gastric emptying
General disorders and administration site conditions: irritability, edema, drug withdrawal syndrome, feeling drunk
Immune system disorders: hypersensitivity
Investigations: gamma-glutamyltransferase increased, alanine aminotransferase increased, aspartate aminotransferase increased
Musculoskeletal and connective tissue disorders: involuntary muscle contractions, sensation of heaviness
Nervous system disorders: hypoesthesia, paresthesia, disturbance in attention, sedation, dysarthria, depressed level of consciousness, memory impairment, ataxia, presyncope, syncope, coordination abnormal, seizure
Psychiatric disorders: euphoric mood, disorientation, restlessness, agitation, nervousness, thinking abnormal
Renal and urinary disorders: urinary hesitation, pollakiuria
Respiratory, thoracic and mediastinal disorders: oxygen saturation decreased, cough, dyspnea, respiratory depression
Skin and subcutaneous tissue disorders: urticaria
Vascular disorders: blood pressure decreased
In the pooled safety data, the overall incidence of adverse reactions increased with increased dose of NUCYNTA™, as did the percentage of patients with adverse reactions of nausea, dizziness, vomiting, somnolence, and pruritus.
10 OVERDOSAGE10.1 Human Experience
Experience with NUCYNTA™ overdose is very limited. Preclinical data suggest that symptoms similar to those of other centrally acting analgesics with mu-opioid agonist activity are to be expected upon intoxication with tapentadol. In principle, these symptoms may particularly appear in the clinical setting: miosis, vomiting, cardiovascular collapse, consciousness disorders up to coma, convulsions and respiratory depression up to respiratory arrest.
10.2 Management of Overdose
Management of overdose should be focused on treating symptoms of mu-opioid agonism. Primary attention should be given to re-establishment of a patent airway and institution of assisted or controlled ventilation when overdose of NUCYNTA™ is suspected. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.
Pure opioid antagonists, such as naloxone, are specific antidotes to respiratory depression resulting from opioid overdose. Respiratory depression following an overdose may outlast the duration of action of the opioid antagonist. Administration of an opioid antagonist is not a substitute for continuous monitoring of airway, breathing, and circulation following an opioid overdose. If the response to opioid antagonists is suboptimal or only brief in nature, an additional antagonist should be administered as directed by the manufacturer of the product.
Gastrointestinal decontamination may be considered in order to eliminate unabsorbed drug. Gastrointestinal decontamination with activated charcoal or by gastric lavage is only recommended within 2 hours after intake. Gastrointestinal decontamination at a later time point may be useful in case of intoxication with exceptionally large quantities. Before attempting gastrointestinal decontamination, care should be taken to secure the airway.
2 DOSAGE AND ADMINISTRATION
As with many centrally-acting analgesic medications, the dosing regimen should be individualized according to the severity of pain being treated, the previous experience with similar drugs and the ability to monitor the patient.
The dose is 50 mg, 75 mg, or 100 mg every 4 to 6 hours depending upon pain intensity.

On the first day of dosing, the second dose may be administered as soon as one hour after the first dose, if adequate pain relief is not attained with the first dose. Subsequent dosing is 50 mg, 75 mg, or 100 mg every 4 to 6 hours and should be adjusted to maintain adequate analgesia with acceptable tolerability.
Daily doses greater than 700 mg on the first day of therapy and 600 mg on subsequent days have not been studied and are not recommended.
NUCYNTA™ may be given with or without food *[see Clinical Pharmacology (12.3)]*.
2.1 Renal Impairment
No dosage adjustment is recommended in patients with mild or moderate renal impairment *[see Clinical Pharmacology (12.3)]*.
NUCYNTA™ has not been studied in patients with severe renal impairment. The use in this population is not recommended.
2.2 Hepatic Impairment
No dosage adjustment is recommended in patients with mild hepatic impairment *[see Clinical Pharmacology (12.3)]*.
NUCYNTA™ should be used with caution in patients with moderate hepatic impairment. Treatment in these patients should be initiated at 50 mg with the interval between doses no less than every 8 hours (maximum of three doses in 24 hours). Further treatment should reflect maintenance of analgesia with acceptable tolerability, to be achieved by either shortening or lengthening the dosing interval *[see Clinical Pharmacology (12.3)]*.
NUCYNTA™ has not been studied in patients with severe hepatic impairment and use in this population is not recommended *[see Warnings and Precautions (5.10)]*.
2.3 Elderly Patients
In general, recommended dosing for elderly patients with normal renal and hepatic function is the same as for younger adult patients with normal renal and hepatic function. Because elderly patients are more likely to have decreased renal and hepatic function, consideration should be given to starting elderly patients with the lower range of recommended doses.
16 HOW SUPPLIED/STORAGE AND HANDLING
NUCYNTA™ Tablets are available in the following strengths and packages. All tablets are round and biconvex-shaped.
50 mg tablets are yellow and debossed with "O-M" on one side and "50" on the other side, and are available in bottles of 100 (NDC 50458-820-04) and hospital unit dose blister packs of 10 (NDC 50458-820-02).
75 mg tablets are yellow-orange and debossed with "O-M" on one side and "75" on the other side, and are available in bottles of 100 (NDC 50458-830-04) and hospital unit dose blister packs of 10 (NDC 50458-830-02).
100 mg tablets are orange and debossed with "O-M" on one side and "100" on the other side, and are available in bottles of 100 (NDC 50458-840-04) and hospital unit dose blister packs of 10 (NDC 50458-840-02).
Store up to 25ºC (77ºF); excursions permitted to 15º – 30ºC (59º – 86ºF) [see USP Controlled Room Temperature]. Protect from moisture.
Keep out of reach of children.
17 PATIENT COUNSELING INFORMATION
Physicians are advised to discuss the following issues with patients for whom they prescribe NUCYNTA™:
17.1 Instructions for Use
Patients should be advised NUCYNTA™ should be taken only as directed and to report episodes of breakthrough pain and adverse experiences occurring during therapy to their physician. Individualization of dosage is essential to make optimal use of this medication. Patients should be advised not to adjust the dose of NUCYNTA™ without consulting their physician *[see Dosage and Administration (2)]*. Patients should be advised that it may be appropriate to taper dosing when discontinuing treatment with NUCYNTA™ as withdrawal symptoms may occur *[see Drug Abuse and Dependence (9.3)]*. The physician can provide a dose schedule to accomplish a gradual discontinuation of the medication.
17.2 Misuse and Abuse
Patients should be advised that NUCYNTA™ is a potential drug of abuse. Patients should protect NUCYNTA™ from theft, and NUCYNTA™ should never be given to anyone other than the individual for whom NUCYNTA™ was prescribed *[see Warnings and Precautions (5.4)]*.
17.3 Interference with Cognitive and Motor Performance
As NUCYNTA™ has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles *[see Warnings and Precautions (5.5)]*.
17.4 Pregnancy
Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during treatment with NUCYNTA™ *[see Use in Specific Populations (8.1)]*.
17.5 Nursing
Patients should be advised not to breast-feed an infant during treatment with NUCYNTA™ *[see Use in Specific Populations (8.3)]*.
17.6 Monoamine Oxidase Inhibitors
Patients should be informed not to take NUCYNTA™ while using any drugs that inhibit monoamine oxidase. Patients should not start any new medications while taking NUCYNTA™ until they are assured by their healthcare provider that the new medication is not a monoamine oxidase inhibitor.
17.7 Seizures

Patients should be informed that NUCYNTA™ could cause seizures if they are at risk for seizures or have epilepsy. Such patients should be advised to use NUCYNTA™ with care *[see Warnings and Precautions (5.7)]*. Patients should be advised to stop taking NUCYNTA™ if they have a seizure while taking NUCYNTA™ and call their healthcare provider right away.

17.8 Serotonin Syndrome

Patients should be informed that NUCYNTA™ could cause rare but potentially life-threatening conditions resulting from concomitant administration of serotonergic drugs (including Serotonin Reuptake Inhibitors, Serotonin and Norepinephrine Reuptake Inhibitors and tricyclic antidepressants) *[see Warnings and Precautions (5.8)]*.

Patients should be advised to inform their physicians if they are taking, or plan to take, any prescription or over-the-counter drugs as there is a potential for interactions *[see Drug Interactions (7)]*.

17.9 Alcohol

Patients should be advised to avoid alcohol while taking NUCYNTA™ *[see Drug Interactions (7.3)]*.

17.10 Medication Guide

See Medication Guide.

Manufactured by:
Janssen Ortho, LLC
Gurabo, PR 00778
Manufactured for:

PriCara®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Raritan, NJ 08869
Revised: June 2009

MEDICATION GUIDE
NUCYNTA™ (new-SINN-tah)
(tapentadol)
immediate-release oral tablets C-II

LABEL IMAGE